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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,637	10/18/2001	James A. Thomson	960296.97877	8584

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/982,637

Applicant(s)

THOMSON, JAMES A.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12,13 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12,13 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on October 18, 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This application is a continuation of 09/761,289, filed January 16, 2001, which is a continuation of 09/106,390, filed June 26, 1998, now US Patent 6,200,806, which is a divisional of 08/591,246, filed January 18, 1996, now US Patent 5,843,780, which is a continuation in part of 08/376,327, filed January 20, 1995, now abandoned.

Applicant's amendment filed April 8, 2004, has been received and entered. Claims 1-11, 14-19 have been canceled. Claims 12 and 20 have been added. Claims 12, 13 and 20 are pending.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12, 13 and 20 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.

The amendment to claim 12 to recite that the embryonic stem cell is a "replicating *in vitro* cell culture" has addressed the basis of the rejection.

Double Patenting

Obvious Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12, 13 and 20 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 5,843,780.

It was indicated in Applicants amendment that a terminal disclaimer was filed with the response, however there is no evidence in the file or present in the filing of Applicant that a terminal disclaimer has been filed. For this reason the rejection is maintained.

It is noted that claim 12 has been amended and again it is noted that the conflicting claims are not identical, however they are not patentably distinct from each other because the instant claims are drawn to a preparation of human embryonic stem cells, which is an obvious species of primate embryonic stem cells encompassed by the claims of '780. In each case the embryonic stem cells have the same characteristics recited in the claims including specific cell surface markers, ability to differentiate and maintenance of genomic integrity. Further, in light of the teaching in the specification each are isolated by the same means and require the same conditions for maintaining the preparations in prolonged culture.

Claims 12, 13 and 20 rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-11 of prior U.S. Patent No. 6,200,806.

It is noted that claim 12 has been amended and no longer the same scope as the scope as that set forth in '806 (see statutory double patenting rejection below). As amended the claims are no longer subject to statutory double patenting, however while the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to a preparation of human embryonic stem cells, which is an obvious species of primate embryonic stem cells encompassed by the claims of '806. In each case the embryonic stem cells have the same characteristics recited in the claims including specific cell surface markers, ability to differentiate and maintenance of genomic integrity. Further, in light of the teaching in the

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specification each are isolated by the same means and require the same conditions for maintaining the preparations in prolonged culture.

Statutory Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 12, 13 and 20 rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-11 of prior U.S. Patent No. 6,200,806 is withdrawn.

As indicated by Applicant the amendment to the claims to encompass a cell that proliferates "without the application of exogenous leukemia inhibitory factor alters the scope of the instant claims from that of the '806 patent.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 13 and 20 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Applicant notes that the basis of the rejection is not clear, and argues that while claims 13 and 20 set forth characteristics of the claimed cell set forth in claim 12, it does not render the claims indefinite. See Applicant's amendment, page 3. Applicant's arguments have been fully considered and found persuasive.

Specifically, the characteristics of the embryonic stem cell set forth in claims 13 and 20 represent additional attributes of the claimed cell but not required by the cell set forth in claim 12. Since the limitations of 13 and 20 further limit the characteristics of the cell of claim 12, Examiner would agree that these claims more narrowly define the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international

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application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12, 13 and 20 rejected under 35 U.S.C. 102(e) as being anticipated by Hardy *et al.* (US Patent 5,541,081) is withdrawn.

The amendment to claim 12 has differentiated the claimed invention from that taught by Hardy *et al.*

Conclusion

No claim is allowed. The claims are free of the art of record, however they are subject to double patenting rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

Joe Woitach
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